

**REMARKS**

**I. Introductory Remarks**

Applicants request reconsideration of this application in view of the foregoing amendments and the following remarks.

Upon entry of the amendments, claims 1-8, 11, 26-34, 36, 38-39, 41 and 44-45 will be pending, with claims 1-8, 11, 27-34, 36, 38-39, 41 and 44-45 being withdrawn from consideration. Claim 26 presently is being amended. No claims presently are being added or canceled.

Claim 26 is amended to state that the identified xylanase retains “at least about 30% of its enzyme activity” in the presence of the inhibitor. Exemplary support for this amendment exists in the specification at Protocol 3 on page 38 and Figure 20, where XM-1 retained about 30% residual activity following exposure to the inhibitor.

As the foregoing amendment does not introduce new matter, entry thereof by the Examiner is respectfully requested.

**II. Right of Priority**

The Examiner acknowledged the claim for foreign priority under 35 U.S.C. § 119, and granted priority to UK 9907805, but denied priority to UK 9828599. Applicants respectfully request reconsideration of the determination regarding the right to priority of UK 9828599.

In denying priority, the Examiner bears an initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize a description of the claimed invention in the original disclosure. *See* MPEP § 2163 (II)(A)(3)(b); *In re Wertheim*, 541 F.2d 257, 263 (CCPA 1976). In this case, however, the Examiner made only a conclusory statement about priority to UK 9828599, without providing any evidence or reasoning to support the statement. Such a conclusory statement does not satisfy the initial burden required to deny an application priority.

Moreover, UK 9828599 actually contains significant support for the claimed invention. For instance, UK 9828599 specifically describes an endogenous endo- $\beta$ -1,4-

xylanase inhibitor isolated from wheat flour (Page 12, line 5 – page 14, line 4; Example 2, page 53, line 12 – page 54, line 25; page 60, line 60 – page 63, line 5) and reports experiments that characterized the properties, both physical and functional, of that inhibitor (Protocol 5, page 55, line 1 – page 59, line 32; page 63, line 6 – page 72, line 6). UK 9828599 further describes assays for determining the effect of the endo- $\beta$ -1,4-xylanase inhibitor on different xylanases (Page 14, line 6 – page 15, line 24; Protocol 3, page 42, lines 1-16) and methods that employ such assays to screen for resistant xylanases (Page 43, lines 13-17 and 22-24). These resistant xylanases are taught to be useful in making bakery products (Page 18, lines 29-31).

For at least these reasons, the present application merits priority to UK 9828599, and Applicants request reconsideration of the Examiner's contrary position.

**III. Claim 26 is Definite, in Accord with 35 U.S.C. § 112, Second Paragraph**

Claim 26 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. In particular, the Examiner stated that the phrase “having a high degree of resistance” is not specifically defined, and is therefore unclear. Applicants respectfully traverse this rejection.

When an ordinarily skilled artisan would understand their meaning, terms of degree, such as “high,” comply with the requirement for claims to be definite. *See* MPEP § 2173.05(b). The present case is such a case. For example, the specification indicates that XM-1 has “a high degree of resistance to the inhibitor.” *See* Protocol 3 on page 38 and Figure 20. In the described inhibitor assay, XM-1 retained about 30% residual activity following exposure to the inhibitor. Thus, an enzyme retaining at least about 30% of its activity has a “high” degree of resistance to the inhibitor. By contrast, the specification indicates that XM-2 and XM-3, which retained about 11% and 14% activity, respectively, have only a “medium” degree of resistance to the inhibitor. *Id.*

To make this measure of resistance explicit in the claims, Applicants have amended claim 26 to recite that the xylanases of interest retain at least about 30% of their enzyme

activity in the presence of the inhibitor. Because the amendment only makes *explicit* what previously was *implicit*, it does not impact the scope of claim 26.

In view of these remarks and the amendment to claim 26, Applicants respectfully request withdrawal of the rejection.

**IV. Claim 26 Complies with the Written Description Requirement of 35 U.S.C. § 112**

Claim 26 was rejected under 35 U.S.C. § 112, first paragraph, for allegedly containing subject matter that was not adequately described in the specification, as filed. More particularly, the Examiner stated that the specification does not evidence possession of a single full length xylanase inhibitor, let alone a “large variable genus” of xylanase inhibitors. Applicants respectfully traverse this rejection.

Applicants may show possession of a claimed invention in a variety of ways, including describing an actual reduction to practice and describing distinguishing identifying characteristics of the invention. *See* MPEP § 2163; *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). In this case, Applicants have shown possession of xylanase inhibitors in both of these ways.

First, the specification contains a detailed example of extracting and purifying a xylanase inhibitor from three different kinds of flour, followed by a demonstration of xylanase inhibition. *See* Example 2.

Second, the specification provides several identifying structural and physical characteristics of xylanase inhibitors. *See* Example 2. For instance, it states that the xylanase inhibitors have a molecular weight of about 40 kDa and a pI of about 8 to about 9.5. *See* page 9, lines 23-24. The specification also states that the inhibitors have at least one of SEQ ID NOS.: 13-19. *See* page 9, lines 30-32. The inventors determined these properties from work on the isolated xylanase inhibitors, which clearly shows possession of the compounds. *See* page 9, line 22 and Example 2.

Claim 26 relates to the use of xylanase inhibitors that specifically have the identifying characteristics of: (i) being obtainable from wheat flour, (ii) having a molecular weight of about 40 kDa, (c) having a pI of about 8 to about 9.5, and (d) comprising one or more of SEQ ID NOS.: 13-19. Thus, the claim tracks what the specification exemplifies, and is not directed to an unsupported “large and variable genus.”

For at least these reasons, Applicants request withdrawal of the rejection.

**V. Claim 26 is Patentable over the Cited Art**

Claim 26 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Debyser et al., *J. Cereal Sci.*, 30: 39-43 (1999) (“Debyser 1”), WO 98/149278 (“Debyser 3”), or Rouau et al., *J. Cereal. Sci.*, 28: 63-70 (1998) (“Rouau”). Applicants respectfully traverse this rejection.

**A. Debyser 1 Does not Render Claim 26 Obvious, as it is not Available as a Prior Art Reference**

Debyser 1 does not constitute prior art, as defined by 35 U.S.C. § 102. Debyser 1 was both submitted for publication and actually published after all three of this application’s British priority documents were filed. Therefore, Applicants request withdrawal of the rejection based on Debyser 1.

**B. Debyser 3 Does not Teach or Suggest the Claimed Invention**

Debyser 3 relates to an inhibitor of xylanolytic and/or  $\beta$ -glucanolytic enzymes and to the use of such an inhibitor in food, feed, and/or beverage technologies. The inhibitor is described as being useful for improving malting and brewing and for making baked and/or extruded cereal products.

Debyser 3 does not teach or suggest, however, that the isolated inhibitor is useful to specifically identify and prepare one or more xylanases having a high degree of resistance to the inhibitor, as required by the claimed invention. Additionally, the reference fails to teach or suggest that xylanases resistant to the inhibitor are useful for preparing dough.

The Examiner acknowledges these deficiencies in Debyser 3 (p. 7, 1<sup>st</sup> ¶ of the Office Action), but asserts that one skilled in the art would be motivated to identify and select xylanases having a high degree of resistance to the inhibitor because it was known that: (a) xylanase inhibitors would negatively affect bread volume, and (b) an inhibitor is present in wheat flour. This line of reasoning constitutes an improper use of hindsight to reconstruct the claimed invention. In the absence of a suggestion within Debyser 3, the present application's teachings cannot be used as a basis for asserting a motivation to modify the Debyser 3 teachings.

Additionally, the xylanase inhibitor of Debyser 3 bears little resemblance to those recited in claim 26. When SEQ ID NOS.: 1 and 2 of Debyser 3 are compared with corresponding sequences in the present application, namely SEQ ID NOS.: 15 and 13, respectively, the degree of identity is only 71% and 53%, respectively. Attached, as Annex 1, is a copy of these sequence comparisons. Debyser clearly provides no motivation for modifying the sequences of its inhibitor to arrive at an inhibitor containing SEQ ID NOS.: 13 or 15 of the claimed invention.

For at least these reasons, Applicants respectfully request withdrawal of the rejection over Debyser 3.

**C. Rouau Does not Teach or Suggest the Claimed Invention**

Rouau contains evidence suggesting the presence in wheat grain of a water-extractable and thermolabile compound that inhibits exogenous hemicellulases.

Rouau does not teach or suggest, however, that the isolated inhibitor is useful to specifically identify and prepare one or more xylanases having a high degree of resistance to the inhibitor, as required by the claimed invention. Additionally, the reference fails to teach or suggest that xylanases resistant to the inhibitor are useful for preparing dough.

As with Debyser 3, the Examiner acknowledges these deficiencies in Rouau (p. 7, 1<sup>st</sup> ¶ of the Office Action), but asserts that one skilled in the art would be motivated to identify and select xylanases having a high degree of resistance to the inhibitor because it was known that: (a) xylanase inhibitors would negatively affect bread volume, and (b) an inhibitor is present in

wheat flour. Again, this line of reasoning constitutes an improper use of hindsight to reconstruct the claimed invention. In the absence of a suggestion within Rouau, the present application's teachings cannot be used as a basis for asserting a motivation to modify the Rouau teachings.

Additionally, Rouau expresses uncertainty regarding the cause of xylanase inhibition. In the section entitled "Conclusions," Rouau states that "it cannot be totally excluded that the inhibitor is of microbial origin". Additionally, in the section entitled "Treatment of Flour Extracts with Pronase and Bovine Serum Albumin," Rouau states that "... it remains a possibility that the inhibitor could be one or several wheat proteases . . ." (emphasis added). Such proteases would function by enzymatically destroying the xylanase protein, and therefore would not constitute a xylanase inhibitor as contemplated by the present invention. The uncertainty expressed by Rouau further undermines that reference's alleged teachings and applicability as a prior art reference.

For at least these reasons, Applicants request withdrawal of the rejection over Rouau.

## **VI. Concluding Remarks**

This application is in condition for allowance, and favorable reconsideration thereof is courteously requested.

If the Examiner believes that an interview would further advance prosecution, he or she is invited to contact the undersigned by telephone .

The Commissioner is hereby authorized to charge any additional fees that may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or

even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

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**ANNEX 1 - Inhibitor Sequence Comparison**

SEQ ID NO.: 13 (PA\*) - G A P V A R A V E A V A P F G V C Y D T K T L G N N

SEQ ID NO.: 2 (D3\*) - X A P V A K M V L P V A M K E X V

SEQ ID NO.: 15 (PA) - L V P A P V T K D P A T S L Y T I P F H

SEQ ID NO.: 1(D3) - K G L P V L A P V T K D I A

\* (PA) = present application

\* (D3) = Debyser 3